

2. (Amended) [Formulation] Prolonged-release formulation in the form of a matrix material-containing compound [with] comprising:

an excipient phase [with] comprising at least one excipient; [and/or]

an active substance phase [with] comprising at least one active substance; and [, characterized in that the]

a matrix material [is chosen from polymers] phase comprising at least one polymer or lipid, wherein in case of cellulose the portion of the matrix material phase of the formulation is 70 to 98%, [and lipids, the polymer phase and/or the lipid phase of the formulation] and wherein the formulation is in the form of spray-dried particles such that the matrix material phase is incoherent and the excipient and/or active substance [phase] phases of the formulation [is] are coherent.

4. (Amended) Formulation according to any one of claims 1, 2 and 19-22 [claim 1], wherein the content of the matrix material phase of the formulation is 1 to 98 %.

5. (Amended) Formulation according to any one of claims 1, 2 and 19-22 [claim 1], wherein the content of the matrix material phase of the formulation is 10 to 95 %.

6. (Amended) Formulation according to any one of claims 1, 2 and 19-22 [claim 1], wherein the content of the matrix material phase of the formulation is more than 15 % and not more than 90 %.

7. (Amended) Formulation according to any one of claims 1, 2 and 19-22 [claim 1], wherein the content of the matrix material phase of the formulation is 40 to 70 %.

8. (Amended) Formulation according to any one of claims 1, 2 and 19-22 [claim 1], wherein the [polymeric] matrix material phase comprises at least one selected from the group consisting of [a] polyacrylate, [and/or a] polymethacrylate, [and/or the lipid phase comprises] naturally occurring, semi-synthetic and synthetic triglycerides or mixtures thereof, mono- and diglycerides by themselves or in a mixture with one another or with triglycerides, naturally occurring and synthetic

RECEIVED
SEP 12 2000
CENTRAL FILE

amended
9. BZ

waxes, fatty alcohols, including their esters and ethers, and lipid peptides[, in particular synthetic mono-, di- and triglycerides as individual substances or in a mixture, specifically hydrogenated fat, glycerol tri-fatty acid esters, specifically glycerol trilaurate, -myristate, - palmitate, -stearate and -behenate, and waxes, specifically cetyl palmitate and cera alba (bleached wax, German Pharmacopeia, 9th edition)] or beeswax].

9. (Amended) Formulation according to any one of claims 1, 2 and 19-22 [claim 1], wherein the [polymer] matrix material phase comprises at least one of a polyacrylate, [and/or] a polymethacrylate, a cellulose derivative, [or] a naturally occurring polymer, and[/or the lipid phase comprises] a naturally occurring lipid.

B3

11. (Amended) Formulation according to any one of claims 1, 2 and 19-22 [claim 1], wherein the excipient phase comprises at least one filler[, in particular chosen] selected from monosaccharides, disaccharides, polysaccharides, sugar alcohols and calcium phosphate, and[/or] at least one binder[, in particular chosen] selected from polyvinyl-pyrrolidone, gelatine, starch paste, celluloses, cellulose ethers and sugars.

Same
9. B3

12. (Amended) Formulation according to any one of claims 1, 2 and 19-22 [claim 1], wherein it is in the form of a compressed unit [which can be prepared by direct compression].

13. (Amended) Process for the preparation of a prolonged-release formulation in the form of a matrix material-containing compound [according to claim 1] comprising:
an excipient phase comprising at least one excipient;
an active substance phase comprising at least one active substance; and
a matrix material phase comprising at least one polymer or lipid, wherein
in case of cellulose materials these cellulose materials are cellulose derivatives,
and wherein the formulation is in the form of spray-dried particles in which the
matrix material is incoherent and the excipient and active substance phases are
coherent, wherein the phases of the formulation are suspended or suspended and

D3 *un* *B3* dissolved together in a liquid to form a suspension, the matrix material phase being insoluble in the liquid, and this suspension is then spray dried.

15. (Amended) Process according to any one of claims 13, 23 and 24 [claim 13], wherein the liquid is an aqueous or organic suspending agent.

16. (Amended) Process according to any one of claims 13, 23 and 24 [claim 13], wherein at least one binder [and/or at least one] wetting agent [and/or [at least one] plasticizer is added to the suspension.


B4 17. (Amended) [Use of the] A formulation [in the form of a matrix material-containing compound] according to claim 1, wherein the spray-dried particles have been formed [for the preparation of] into larger matrix units with prolonged release properties [by known processes].

57 18. (Amended) [Use of the] A formulation [in the form of a matrix material-containing compound] according to claim 1, [for the preparation of] which as been formulated in the form of tablets [and/or larger matrix units with prolonged release properties by means of direct compression.


Please add new claims 19-25 as follows:

Sub *20* *B6* 19. Prolonged-release formulation in the form of a matrix material-containing compound comprising:
an excipient phase comprising at least one excipient; and
a matrix material phase comprising at least one polymer or lipid, wherein in case of cellulose materials these cellulose materials are cellulose derivatives, and wherein the formulation is in the form of spray-dried particles in which the matrix material phase is incoherent and the excipient phase is coherent.

20. Prolonged-release formulation in the form of a matrix material-containing compound comprising:



an active substance phase comprising at least one active substance; and
a matrix material phase comprising at least one polymer or lipid, wherein
in case of cellulose materials these cellulose materials are cellulose derivatives,
and wherein the formulation is in the form of spray-dried particles in which the
matrix material phase is incoherent and the active substance phase is coherent.

- 
21. Prolonged-release formulation in the form of a matrix material-containing compound comprising:

an excipient phase comprising at least one excipient; and
a matrix material phase comprising at least one polymer or lipid, wherein
in case of cellulose the portion of the matrix material phase of the formulation is
70 to 98%, and wherein the formulation is in the form of spray-dried particles such
that the matrix material phase is incoherent and the excipient phase of the
formulation is coherent.

22. Prolonged-release formulation in the form of a matrix material-containing compound comprising:

an active substance phase comprising at least one active substance; and
a matrix material phase comprising at least one polymer or lipid, wherein
in case of cellulose the portion of the matrix material phase of the formulation is
70 to 98%, and wherein the formulation is in the form of spray-dried particles such
that the matrix material phase is incoherent and the active substance phase of the
formulation is coherent.

23. Process for the preparation of a prolonged-release formulation in the form of a matrix material-containing compound comprising:

an excipient phase comprising at least one excipient; and
a matrix material phase comprising at least one polymer or lipid, wherein
in case of cellulose materials these cellulose materials are cellulose derivatives,
and wherein the formulation is in the form of spray-dried particles in which the
matrix material is incoherent and the excipient phase is coherent, wherein the
phases of the formulation are suspended or suspended and dissolved together in